

CLAIMS

1. Tamsulosin hydrochloride, ((R)-5-(2-(2-(2-ethoxyphenoxy)ethylamino)propyl)-2-methoxybenzenesulphonamide) hydrochloride, in the amorphous form.
2. Tamsulosin hydrochloride in the amorphous form according to claim 1 characterised in that the DSC thermogram thereof exhibits an exothermic peak at about 100 °C.
3. Tamsulosin hydrochloride in the amorphous form according to claim 1 characterised in that the IR spectrum thereof exhibits a band at about 3449 cm^{-1} .
4. Tamsulosin hydrochloride in the amorphous form according to claim 3 characterised in that the IR spectrum thereof exhibits the bands substantially as shown in Table 1.
5. Tamsulosin hydrochloride in the amorphous form according to claim 1 characterised in that the X-ray powder diffractogram thereof exhibits the absence of discrete diffractions which are characteristic of crystalline forms.
6. A process for the preparation of the amorphous form of tamsulosin hydrochloride characterised in that it comprises lyophilization of a solution of tamsulosin hydrochloride.
7. The process for the preparation of amorphous tamsulosin hydrochloride according to claim 6 wherein said solution of tamsulosin hydrochloride is aqueous solution.
8. A process for the preparation of the amorphous form of tamsulosin hydrochloride characterised in that it comprises spray-drying of a solution of tamsulosin hydrochloride.
9. The process for the preparation of amorphous tamsulosin hydrochloride according to claim 8 wherein said solution of tamsulosin hydrochloride is aqueous solution.

10. A pharmaceutical formulation comprising tamsulosin hydrochloride and one or more pharmaceutically acceptable excipients characterised in that it comprises tamsulosin hydrochloride in the amorphous form.
11. A pharmaceutical formulation comprising tamsulosin hydrochloride characterised in that said tamsulosin hydrochloride is prepared by the processes according to claims 6 to 9.
12. A method of preparing a pharmaceutical formulation of tamsulosin hydrochloride in the amorphous form comprising combining an amount of tamsulosin hydrochloride in the amorphous form with pharmaceutically acceptable excipients.
13. Use of tamsulosin hydrochloride in the amorphous form for the preparation of a pharmaceutical formulation together with pharmaceutically acceptable excipients.
14. Use of tamsulosin hydrochloride in the amorphous form for the preparation of a medicament for the treatment of benign prostatic hyperplasia.
15. A method of treating benign prostatic hyperplasia which comprises administering a therapeutically effective amount of amorphous tamsulosin hydrochloride in conjunction with a pharmaceutically acceptable diluent or carrier.